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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,279	03/19/2001	Keith Wood	10743/6	1759
757	7590	11/28/2003	EXAMINER	
BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60611			LEARY, LOUISE N	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/813,279	WOOD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Louise N. Leary	1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☒ Claim(s) 15, 18, 30, 42 and 59-64 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

1. Original claims 1-59 and newly added claims 60-64 are pending in this application.
2. The first supplemental information disclosure statement, filed September 29, 2003, which lists references already of record in this application has been made of record.
3. The examiner acknowledges the typographical error which resulted in an incomplete listing of the claims rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Simpson et al (US 5,004,684) in the Office Action dated June 3, 2003. The claims rejected and the claims objected to were correctly listed on form PTO-326.
4. Claims 1-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because the metes and bounds of the phrase "wherein the reagent composition is capable of maintaining..." cannot be determined.

Alternatively, the phrase "wherein the reagent composition is capable of maintaining..." is open-ended and does not describe a definite activity. Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14,16-17,19-29, 31-41, and 43-58 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Simpson et al (US 5,004,684).

Claims 1-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Simpson et al (US 5,004,684).

Simpson et al disclose a bioluminescent method for assaying of ATP in a sample by contacting a reagent composition comprising a cationic surface active agent to the sample, adding an amount of a non-ionic surface active agent, followed by determining the ATP released into the sample using luciferase-luciferin reagent. See column 6, lines 53-68 and columns 7-8, lines 1-18. In regards to the limitations in claim 1, step (a) which recites adding a reagent composition comprising one or more detergents to the sample, Simpson et al disclose a method step whereby " the releasing agent is preferably a cationic surface active agent which is preferably contacted with a non-ionic surface active neutralizing agent". See column 3, lines 16-19. Also, Simpson et al

disclose that ATP extracting assay methods have previously used cationic surface agents, ionic detergents and non-ionic detergents alone and in combination. See column 2, lines 1-68. With respect to the enzyme stabilizing agent described in instant claim 8, Simpson et al disclose the addition of EDTA to the sample mixture. Note column 3, lines 8-68 and column 4, lines 1-68. Simpson et al also disclose the methods use cationic detergent in amounts equal to or greater than 0.1% (w/v) described in the instant claims. See column 3, lines 46-68, and columns 5-6, lines 1-68 of each. With respect to the detergents described in instant claim 14, Simpson et al disclose extracting ATP from cells of microorganisms using the cationic detergent dodecyl trimethyl ammonium bromide. See column 2, lines 22-26. Thus, Simpson et al disclose all the limitations of the methods claimed except for addressing the instant claim limitation "the reagent composition is capable of maintaining at least 30% activity for at least 1 hour".

However, regarding the instant claim limitation "the reagent composition is capable of maintaining at least 30% activity for at least 1 hour", Simpson et al disclose luminescence assay methods for detecting and quantifying ATP in a sample using one or more detergents and luciferase-luciferin reagent as claimed in the present invention. Hence, the limitation "the reagent composition is capable of maintaining at least 30% activity for at least 1 hour" is deemed to be an inherent property of the reaction mixture in the ATP assays disclosed by the Simpson et al reference because Simpson et al disclose methods that use the same starting materials and reaction conditions claimed

in the present invention. Therefore, the Simpson et al disclosure anticipates or renders obvious the claimed invention.

The burden of proof is on applicants to show patentably distinct differences between the methods disclosed by Simpson et al and the methods claimed in the present invention.

6. Claims 15, 18, 30, 42, and 59-64 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 9:30 to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

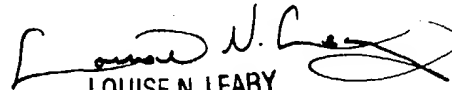
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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LOUISE N. LEARY  
PRIMARY EXAMINER

November 15, 2003